

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	§	
TRACEY A. CAVATO	§	Confirmation No.: 5924
TIMOTHY R. COOMBE	§	
SCOTT C. JOHNSON	§	Group Art Unit: 1638
	§	
Serial No.: 10/523,290	§	Examiner: Anne R. Kubelik
	§	
Filed: October 19, 2005	§	Atty. Dkt. No.: 11899.0262.PCUS00
	§	
For: Corn Event PV-ZMIR13 (MON863) Plants and	§	
Compositions and Methods for Detection	§	
Thereof	§	

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

REPLY TO REQUEST FOR INFORMATION UNDER 37 CFR §1.105

Sir:

In response to the Request for Information under 37 CFR §1.105 dated February 19, 2009, having an extended period for response expiring July 19, 2009, Applicants submit the following information as requested in the form of a declaration under 37 CFR §1.132. A petition for a three-month extension of time is filed concurrently.

Declaration of James D. Colyer Under 37 CFR §1.132

I, James D. Colyer, declare the following:

1. I earned a Bachelors of Science degree in Agronomy from Southern Illinois University in 1983. I have been employed at Monsanto Company since 1984 and as a direct employee since 1989. Monsanto Company is the parent company wholly owning Monsanto Technology LLC, the assignee of the above captioned patent application. I have held a number of different positions during my employment with Monsanto Company, including the positions entitled Research Biologist Product Support/Formulations and Bioevaluations. My present position is entitled Regulatory Agronomist/Oil Seeds Processing Lead/ Field Project Manager.

My present position has included the responsibility as Production Coordinator for the Monsanto Regulatory field trials used to produce MON863 corn grain during 2001 and 2002 for use in subsequent animal feeding trials. In addition, my responsibilities with respect to the MON863 events included ensuring that the required United States Department of Agriculture (USDA)-APHIS compliance regulations were met as specified for regulated field evaluation purposes and within Federal, State, and Local Regulated Materials requirements described herein below.

2. I have read, I understand, and I am familiar with the issues related to the Grant *et al.* paper (2003, J. Dairy Sci. 86: 1707-1715) with respect to the Request for Information under 37 CFR §1.105 dated February 19, 2009 in the above captioned application. I also understand that the effective filing date for the above captioned application corresponds to the date the provisional application, to which the above captioned application claims priority, was filed, and that the provisional application was filed on July 29, 2002.

3. As a result of my employment with Monsanto Company and the nexus that my employment positions have had with respect to the development and commercialization of the referenced transgenic event MON863, it is my opinion that there was no sale or other public distribution of the claimed plant/seed anywhere in the United States prior to the effective filing date of the above captioned application based on the following reasoning.

4. The MON863 seed used in the Grant *et al.* paper was supplied by Monsanto Company under a Production Plan. MON863 grain was grown and held under identity preserved conditions at University of Nebraska at Lincoln in strict compliance with the USDA-APHIS regulations to support animal feeding studies.

I was involved in the development of the Production Plan as well as in the monitoring of the grain production for the subsequent animal studies. The Production Plan provided the following confidentiality notice to the recipient of the regulated materials:

All information regarding the identity of this crop, associated samples, production plots and data must be kept strictly confidential. No raw data, worksheets, observations, data or information summaries, reports or other information related to this Production Plan may be revealed or released to any third party without prior notification and authorization of Monsanto Company.

Recipient of MON863 seed was provided with a Regulatory Compliance Packet containing instructions for conducting studies using the regulated transgenic seed. Because the regulated transgenic seed were restricted articles under USDA and the Environmental Protection Agency (EPA) regulations, strict compliance with regulatory procedures set forth in the Compliance Packet was required. Regulated transgenic seed were only shipped to a recipient upon receipt by Monsanto of a USDA Interstate Movement and Release Permit. Regulatory Compliance Packet provided to recipients of the regulated transgenic seed notified each recipient

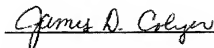
of his or her obligations under federal regulations for such regulated articles, requiring that the recipients restrict access to the seed and materials generated from the seed, restrict movement of the seed or plant materials grown from the seed, maintain the seed and the plots where the seed were sown under secure conditions, insure that the seed and any plants or produce from the plants be kept from entering into any stream of commerce, isolate fields where the seed are planted to restrict the movement of pollen to related species, destroy remaining plant material in fields where the seed were planted, limit replanting in consecutive seasons in the same field and monitor for and destroy volunteer plants that grow in subsequent seasons, and report to Monsanto Company any alterations or deviations from these requirements so that such information reported by a recipient could also be reported to the appropriate federal regulatory authorities requiring such compliance standards. Upon the conclusion of any such regulated field trials, the recipients of such regulated seed were required to execute a statement acknowledging that he/she had received, read, and understood the Monsanto company and USDA Compliance Package for each regulated trial being conducted for Monsanto Company and complied with the principles and policies set forth in the USDA-APHIS Compliance Packet.

5. It is my understanding that animal feeding trials did not begin until after the Federal Drug Administration (FDA) granted approval of MON863 as food/feed on Dec 31, 2001. Monsanto submitted a request for a seed increase registration to EPA on March 19, 2001. The registration for MON863 was granted by EPA on February 24, 2003. There was no commercial planting of the product allowed before EPA's approval was granted. It should be noted that EPA's approval was granted after the effective filing date of the above captioned patent application. It is believed that because of the strict regulatory requirements placed on any

movement or field trial of regulated seed containing the MON863 event trait, no sale, offer for sale, or other activity caused the article to be publicly available existed prior to February 2003 when the final federal regulatory approval was granted.

6. Therefore, based on my experience with this transgenic event and its development, the regulatory approval process through which the event traversed, its commercialization history, and the facts that I declare herein above, it is my opinion that no sale or offer for sale for the MON863 transgenic corn event was made prior to the effective date of the instant application, and that there was no public use of this material prior to the effective date of the instant application. That is, corn event MON863 was not publically available in any form, commercially or otherwise, prior to the effective filing date of the instant application.

7. I hereby declare that all statements made herein are of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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James D. Colyer
Monsanto Company, BB3G
800 North Lindbergh Blvd.
St. Louis, MO 63167

Date: July 17, 2009_____